

Remarks

Claims 1, 2 and 7 have been canceled. Claims 3, 4, 5 and 6 remain in the application. Reconsideration of this application and the amendments is requested.

Claim 3 has been amended to incorporate the language of claims 1 and 2 to become an independent claim. The Examiner has indicated that this claim and claim 4 would be allowable in independent form. The language is not exactly identical to the combination of all three claims in that the support collar has been omitted. The functional language of the claims relates to the, "securing nut," which makes the ultimate connection and this language has been retained.

Claim 5, directed to a fixation system, has been amended to follow the terminology of the claim 3 and should also be allowable.

Rejections under judicially created doctrine of obviousness type double patenting

Claims 1 - 7 stand rejected as not patentably distinct from claims 1 and 2 of U. S. Patent No. 6,623,485. The basis of this rejection is not understood. The instant claims are directed to structure not disclosed, illustrated or suggested in the '485 patent. The instant claims are not broad enough to cover the claimed device in the '485 patent. There is no secondary reference cited to support the allegation that the improvements are obvious in view of the prior art.

It is presumed that the claims of the patent do not anticipate the instant claims. And, indeed, they cannot because there is no disclosure in the original application to cover the structure now being claimed. And, that is why this application has the status of a continuation-in-part. Given this situation, the Examiner cannot dismiss the crux of the

instant improvement without some corroboration from the prior art that the improvement is old. Further, the obvious-type rejection requires the same motivation as any other obviousness rejection.

The instant applicant cannot be discriminated against because he has a prior patent. He is entitled to protect his improvements just as any other inventor is entitled to patent improvements on the '485 device.

Contrary to the basis of the rejection, the subject matter claimed in the instant application was not fully disclosed in the patent and that is the reason why applicant was prevented from fully prosecuting the broad claims in the patent. Allowance of the instant claims would not extend the monopoly of the original patent.

Rejections under 35 USC 103

Claims 1, 2 and 5 - 7 stand rejected as obvious in view of Mullane and Ganem. Mullane teaches a spinal fixation system similar to the instant system. Mullane's pedicle screw has a head with an outer ball end. The interior of the ball end has a tubular cavity with threads in the wall. An externally threaded retention collet is telescoped over the pedicle screw and threaded into the cavity. The dome shaped interior of the collet and the toggle bolt ball end form a friction fit when the securing nut is tightened on the exterior threads of the toggle bolt. The problem is that it is exceedingly difficult to machine a ball and an dome to have the same dimensions. There are voids in the contacting surfaces reducing the strength of the connection. The circular line about the mouth of the collet is probably the major portion of the connection. This allows the toggle bolt to move under the strongest tightening of the

securing nut. Further, the machining required for threads of the collet is very precise, also. The expansion of the collet determines the strength of the threaded connection.

The Doubler patent teaches an alternative connection that is considered an improvement of the line connections of the Mullane system. Instead of a collet, Doubler uses a split ring which is much easier to make and requires much less precise machining. Rather than using a thread connection between the collet and the pedicle screw, Doubler uses corresponding conical surfaces to form an area contact in place of a line to increase stability of the joint. Within the collet, the interior wall has a spherical shape with pronounced rings near the bottom and top of the collet to engage the ball end of the toggle bolt. This produced a system that was easier and cheaper to make and had a stronger and more stable connection between the toggle bolt and the pedicle screw.

The instant claims are directed to another iteration that is less expensive and stronger than the others. In the claimed embodiment, the ball end of the toggle bolt has been replaced with a conical shape. The interior of the split retention ring has been formed with a corresponding taper to form an area seal to prevent angular displacement between the toggle bolt and the collet. The interior of the pedicle screw ball end is also spherical with pronounced rings near the bottom and top to insure at least two line connections longitudinally spaced between the collet and the pedicle screw to prevent angular displacement.

The combination of Mullane and Ganem does not teach the claimed invention. Both of the references have a spherical connection between the bone engaging member and the linking member. In contrast, the claimed device has a conical end on the linking

member which fits with a complementary tapered retention ring. Neither of the references show such a structure nor is one suggested by them. Therefore, the combination does not teach the claimed invention.

On the one hand, there is a fundamental difference between a washer (Ganem) and an universal connector (Mullane). The split ring washer of Ganem must rely on the torque forces of the bone screw for compressing the plate and the screw together with the washer in between. The collet connector of Mullane requires no additional torque to be applied to the bone screw but becomes fixed in place due to expansion forces pulling the components apart. These mutually exclusive functions would not lead one of ordinary skill in the art to look to lock washers for modifying a collet.

On the other hand, assuming, *in arguendo*, that Ganem suggests splitting the collet of Mullane, the modification would not affect the operation of the Mullane device. The interrupted threads of the split Mullane collet would continue to perform the function of holding the collet in place even though it may be weakened. Nothing in such a combination would teach the use of complementary tapers for locking the elements together.

phone 561 625-6575
fax 561 625-6572

McHale & Slavin, P. A.
2855 PGA Blvd.
Palm Beach Gardens, FL 33410



C. Fred Rosenbaum
Registration No. 27110